

## REMARKS

The amendments to the claims do not add new matter. Applicants have amended claim 1 to recite that the claimed xenograft BTB implant is “suitable for fixation in a bone tunnel during orthopedic surgery on a human.” Support for the recitation to fixation in a bone tunnel is found throughout the specification, including at page 6, lines 23-24 (“Once the BTB is properly situated in tunnels 462 and 466, the BTB 430 is secured in the recipient bone by interference screws 440.”). Support for the xenograft BTB being suitable for a “human” is found in the specification at page 2, last ¶ (“the subject invention pertains to a method of conducting orthopedic surgery on a human or an animal . . .”). The amendment to claim 1 clarifies that the “groove” in the bone blocks is a “machined” groove as opposed to a crushed groove. Support for the groove being machined is found throughout the specification, including at page 2, lines 11-14 (“In a specific aspect, the subject invention pertains to a bone tendon bone graft useful in orthopedic surgery comprising one or more bone blocks, and a tendon attached to said one or more bone blocks; wherein said one or more bone blocks is **cut** to provide a groove sufficient to accommodate a fixation screw”); at page 4, last ¶ (“To facilitate placement of a fixation screw, the dowels are preferably **machined** down the length of the bone block **to form radius cuts** 115, 125. The **radius cuts** 115, 125 aid in the attachment of the graft to recipient bone because they **provide a groove** to position a **fixation screw**, which results in increased surface area at the contact between the bone block and the screw.”) Claim 1, which also recites “each of said first bone block and said second bone block is dowel shaped and sized for pulling through said bone tunnel, is supported throughout the specification, including at page 6, lines 20-24 (“To aid in guiding the BTB 430 through tunnel 462, sutures 460 are optionally engaged to **bone block 432**, which allows the surgeon **to pull the BTB 430 through tunnel 462** where the sutures 460 can then be removed”); emphasis added in bold.

Claim 36, which recites that the “dowel shaped first bone block has an end comprising a tapered region,” is supported throughout the specification, including at FIG. 8 and the description of FIG. 8 at page 8, lines 18-20 (“The bone block portion 810 comprises two ends 812 and 814 which both comprise a tapered region 816 and 818, respectively”); and at FIG. 2 and the description of FIG. 2 at page 5, lines 14-20 (“Bone

block 212 is a **dowel that has a proximal tapered region 216** in relation to tendon 200, and bone block 214 is pre-shaped into a **dowel that has a distal tapered region 218** in relation to tendon 200. FIG. 2C illustrates a preferred version of the invention, which has a bone block 230 with a **proximal tapered region 239** and a groove 238 positioned on the bone block 230. This version also comprises a second bone block 234 with a **distal tapered region** and a groove 236 positioned on bone block 234 as well.”); emphasis added in bold.

Claim 38 was amended to parallel the amendments to claim 1. Support for the amendments to claim 38 are the same as for claim 1. Accordingly, the amendments to the claims do not add new matter.

### **Summary of the Bases for Rejection**

Claims 1, 2, 4, 8-9, and 31-40 are rejected under 35 U.S.C. §103(a) for being allegedly unpatentable over U.S. Pat. 5,067,962 (“Campbell”) in view U.S. Patent No. 5,961,520 (“Beck”).

#### **I. 35 U.S.C. §103(a) Campbell in view of Beck**

Claims 1, 2, 4, 8-9, and 31-40 are rejected under 35 U.S.C. §103(a) for being allegedly unpatentable over U.S. Pat 5,067,962 (“Campbell”) in view U.S. Patent No. 5,961,520 (“Beck”). According to the Patent Office, Campbell discloses a “xenograft replacement ligament comprising a bone-ligament-bone attachment with a naturally occurring [ligament to bone] attachment (see abstract and Fig. 3).” The Applicants agree. The Patent Office further contends that “Figure 3 [of Campbell] discloses bone blocks shaped into a dowel.” [Official Action at page 4.] The Applicants respectfully disagree. The Patent Office admits, “Campbell et al does not disclose a groove along the length of each bone block.” [Official Action at page 4.] The Applicants agree.

To make up for the lack of a groove in Campbell, the Patent Office cites to Beck. According to the Patent Office, Beck “discloses an artificial ligament comprising an anchoring system made of bone (see col. 6, lines 36-39) and having a groove along the length (see Fig. 2, see element 17) for the purpose of inserting an attachment screw and attach the attachment system to the patient’s bone.” [Official Action at page 2.] The

Patent Office then concludes that “[i]t would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the bone blocks of the Campbell et al. reference with **the longitudinal groove (see surface 17) of the Beck, Jr. et al. reference**, in order to insert an attachment screw and attach the attachment system to the patient’s bone.” [Official Action at page 5.] The Applicants respectfully disagree.

**A. Campbell does not disclose “a dowel”**

As noted above, a factual basis underlying the Patent Office’s conclusion of obviousness is that “Figure 3 [of Campbell] discloses bone blocks shaped into a dowel.” [Official Action at page 4.] The Applicants respectfully disagree. By definition, a “dowel” is understood as meaning a peg or pin of **uniform** or substantially uniform circular diameter for fitting into hole of a corresponding diameter:

**dowel-** a headless or barbed pin usually of **circular section** fitting into corresponding holes in abutting pieces to act as a temporary fastening or to keep them permanently in their proper relative position; *also* : a **round rod** or stick used especially **for cutting up into dowels**.

[Exhibit A: Webster’s Third New International Dictionary of the English Language Unabridged, Merriam-Webster Inc., Publishers, Springfield, MA, 2002 at page 681; emphasis added in bold.]

\* \* \*

**dowel-** a pin, **usually round**, fitting into two adjacent pieces to prevent their slipping or to align them.

[Exhibit B: Webster’s Unabridged Dictionary of the English Language, Portland House, New York, 1983 at page 430; emphasis added in bold.]

\* \* \*

**dowel-** a peg or pin of wood, metal, etc., usually fitted into corresponding holes in two pieces to fasten them together.

[Exhibit C: Webster’s New World Dictionary, Second College Edition, Ed, Prentiss Hall Press, 1986 at page 422; emphasis added in bold.]

Thus, each of these dictionary definitions defines a dowel as having a “circular” cross section or being a “pin”. Moreover, each of these three dictionary definitions includes in the definition a picture, showing the “dowel” as being a pin of uniform or substantially uniform diameter so as to have side walls that are parallel or substantially parallel. Consistent with this, wooden “dowels” are commercially available in the hardware store in 3 foot lengths in a range of uniform “diameters” such as 1/8”, 3/16”, 1/4”, 3/8”, 1/2”, 5/8”, 3/4” etc.

In contrast to a “dowel,” Campbell discloses a BTB having bone blocks that are “frustoconical” shaped, i.e., that are cone shaped with a blunt end.

**frustum** – the part of a **conical** solid left after cutting off a top portion with a plane parallel to the base.

[Exhibit B: Webster’s Unabridged Dictionary of the English Language, Portland House, New York, 1983 at page 572; emphasis added in bold.]

Referring to the figure entitled “frustum of a cone” shown in Exhibit B at page 572, it can be seen that it is identical to the bone blocks of Campbell. Moreover, the term “frustoconical” is well-known in U.S. patent parlance for describing truncated cone-shapes, such as the truncated conical bone blocks of Campbell:

The term “frustoconical surface” is defined by straight lines intersecting the edge of the annular base of the stopper and the apex so the resulting surface tapers evenly between the base and truncated tip surfaces.

[Exhibit D: U.S. Pat. 4,826,029 (Skoglie), entitled “Stopper and method of use in association with wine barrels,” at col. 1, lines 54-57.]

In Skoglie, the term “frustoconical surface” referred to the surface shape of stoppers that were placed in the filling hole in a wine barrel to seal the hole. See Exhibit D: Skoglie at page , FIGS. 3, 4 and 6, showing the frustoconical shaped stoppers. Thus, by definition, a “dowel” has side walls that are parallel or substantially parallel, whereas a “frustoconical” shaped object has sidewalls that taper significantly such that the taper is visually apparent,

as in the bone blocks of Campbell, the figure in the dictionary definition, or the stoppers of U.S. Pat. 4,826,029 (Skoglie). Accordingly, Campbell does not disclose “bone blocks shaped into a dowel.” Thus, the Patent Office’s conclusion of obviousness, which is based upon this erroneous finding of fact, is legally erroneous.

As an additional note added in proof of the difference between “plug” and “dowel” shapes, the Applicants’ specification discloses that “The extracted bone blocks 330, 340, and 350 are generally **shaped** like a **plug** or **dowel** and are preferentially further shaped by conventional methods known in the art.” [Specification at page 6, lines 7-9; emphasis added in bold.] However, Applicants have amended independent claims 1 and 38 to reflect that the claimed xenograft BTBs have bone blocks that are shaped like “dowels,” thereby excluding “plugs” such as the bone plugs of Campbell.

For all these reasons, claims 1, 2, 4, 8-9, and 31-40 would not have been obvious under 35 U.S.C. §103(a) over U.S. Pat 5,067,962 (“Campbell”) in view U.S. Patent No. 5,961,520 (“Beck”).

**B. Claims 1, 2, 4, 8-9, and 31-40 would not have been obvious because Campbell “teaches away” from the use of dowels and the bone tunnels in which they are used**

Separately, “[a] prior art reference may be considered to teach away when ‘a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or **would be led in a direction divergent from the path taken by the applicant.**” *Monarch Knitting v. Sulzer*, 45 USPQ2d 1977, 1984 (Fed. Cir. 1998); emphasis added in bold. *See In re Fine*, 5 USPQ2d 1596, 1599 (Fed. Cir. 1988) *citing W.L. Gore & Assoc. v. Garlock, Inc.*, 220 USPQ 303, 311 (Fed. Cir. 1983) (“error to find obviousness where references ‘diverge from and teach away from the invention at hand’”). In the present case, claims 1 and 38 have been amended to recite that the naturally attached bone blocks of the xenograft BTB implant are “dowel shaped and sized for pulling through said bone tunnel” (claim 1) or “sized and shaped to be pulled through said bone tunnel” (claim 38). Applicants will show that Campbell teaches away from the claimed implants that are sized and shaped to be suitable for pulling through the bone tunnels in the endosteal technique.

The two references relied upon by the Patent Office take divergent approaches to anterior cruciate ligament (ACL) repair. Campbell is directed to “**open**” technique for ACL repair wherein the knee is articulated (spread open), and to a specific BTB implant designed for use with open knee surgery, wherein the implant has **plug** shaped bone blocks that form a **seal fit** in plug shaped holes in the opposing tibia and femur. [Larsen Declaration at ¶6.] In contrast, Beck (U.S. Pat. 5,961,520) [and Simon (U.S. Pat. 5,951,560) Mahoney (U.S. Pat. 5,282,802) and Roger (U.S. Pat. 5,383,878)] are directed to the closed or endosteal technique for ACL repair and to a variety of specific implants for use in that technique wherein the implants (and their bone blocks or plastic blocks) slideably fit in bone tunnels drilled through the tibia and into femur and are fixed therein by interference screws. [Larsen Declaration at ¶6.]

Campbell teaches BTB implant having a stopper or plug (frustoconical) shaped bone block that forms a seal fit with a correspondingly stopper shaped hole in the recipient’s bone. Campbell teaches away from a BTB implant having bone blocks that slideably fit in bone tunnels and that have a sufficient gap between the bone block and the bone tunnel to accommodate an interference screw. However, as was pointed out in both the Larson Declaration at ¶ 8 and in the Applicant’s RCE and Response to the prior Official Action, the Patent Office has ignored Campbell’s teaching away from the use of slideable implants in bone tunnels because they allow synovial fluid to leak into the bone.

In particular, Campbell begins teaching at column 1 of his specification that the “**manner**” and the “**details of prosthesis construction**” are “**important**” and that success depends upon “**proper attachment**”:

Replacement ligaments can restore performance where native structures rupture beyond repair. But **success depends on proper attachment** to the host bone. Thus, the **manner** in which this is done and the related **details of prosthesis construction** are **important**.

[Campbell at col. 1, lines 13-17; emphasis added in bold.]

Thus, when Campbell distinguishes his “**construction**” and mode of “**attachment**” from the prior art method of using bone tunnels, Campbell’s teachings cannot be ignored or be said “not to teach away.” *See In re Hedges*, 228 USPQ 685, 687 (Fed. Cir. 1986) (“It is

impermissible within the framework of section 103 to pick and choose from any reference only so much of it as will support a given position, to the exclusion of other parts necessary to the full appreciation of what such reference fairly suggests to one of ordinary skill in the art.”).

Campbell’s plug shaped “construction” and mode of “attachment” **teach away** from the use of looser fitting BTB implants that slide in and are fixed in **endosteal tunnels drilled in the femur and tibia**. Specifically, Campbell points out several problems with the slideable implants and their manner of attachment, including “ligament stretch, impaired performance, spicules that abrade ligaments, and synovial fluid in the intraosseous space.”:

Consider, for example, an injured knee joint having a damaged anterior cruciate ligament. Attachment of a replacement ligament according to **existing techniques** may involve **forming tunnels** in the **femur and tibia (the host bones)**. The tunnels are formed so that each extends through one of the host bones from an entrance or proximal end of the tunnel at the natural ligament attachment site to an exit or distal end of the tunnel at an outer surface of the host bone.

Each end of the replacement ligament is passed through one of the tunnels, from the proximal end to the distal end where it is anchored to the outer surface of the host bone by such means as stapling. This results in the replacement ligament spanning the intra-articular region between the natural attachment sites somewhat like a natural ligament, but it also results in certain problems that need to be overcome.

For example, the **replacement ligament extends beyond the natural attachment sites and all the way through the tunnels** to the outer surfaces on the other side of each host bone. This **results in the replacement ligament being able to stretch over a greater length than a natural ligament** (from the outer surface of the femur to the outer surface of the tibia), and this **impairs performance**.

In addition, **formations** such as **bone spicules** can form at the entrance to each of the tunnels. These tend to **abrade the replacement ligament**, cause **fatigue** of the material, and break off particles which can cause **irritation**.

Furthermore, the **tunnels** provide access to the host bone interior. As a result, **synovial fluid can migrate from the intra-articular region between host bones into the bone tunnels**. Thus, any activity in the intra-articular region, such as **infection**, can be easily **communicated** into the bone interior and result in **intra-osseous complications**. Similarly, activity within the bone can be easily communicated to the intra-articular region.

Consequently, it is desirable to have a **new** and improved **replacement ligament** and **attachment method** that overcomes these concerns.

[Campbell at col. 1, lines 18-58; emphasis added in bold.]

Thus, Campbell teaches that **both** the “**details of prosthesis construction**” of his plug shaped BTB implant, and the “**manner**” of its attachment are “**important**” and required to overcome these concerns. [See Campbell at col. 1, lines 13-17; emphasis added.]

Campbell’s replacement ligament (BTB implant) is shown in FIG. 3 of Campbell. Campbell’s BTB implant has stopper shaped (frustoconical) bone blocks naturally attached to opposing ends of a tendon. In FIG. 4, Campbell discloses the stopper shaped bone blocks of his implant of FIG. 3 positioned in the corresponding stopper shaped holes in the tibia and the femur of a patient. As seen in FIG. 4, when the stopper shaped bone plug is fitted in its correspondingly shaped hole, there is a complete seal between the donor bone and the recipient bone in the joint and there is no space between the donor bone and the recipient bone into which “synovial fluid” can migrate. To maintain this seal, Campbell disclosed the use of a pin that was transversely inserted into a hole drilled through the outside lateral surface of the donor bone (away from the joint and its synovial fluid) and through the fitted implant. Moreover, Campbell contrasts his implant and its manner of attachment to those other implants that use “bone tunnels.” [Campbell at col. 1, lines 18-55 (quoted above).] Thus, Campbell teaches an implant structure and a method of implantation that provides a solution to the problem of **synovial fluid migrating “from the intra-articular region between host bones into the bone tunnels.”** Moreover, Campbell discloses that both his “**manner**” of implantation and “the related **details of prosthesis construction** are **important**.” [Campbell at col. 1, lines 13-17.] By Campbell’s use of the word “**important**” in relation the details of “**prosthesis**



**construction,”** Campbell teaches one skilled in the art not to make changes to the structure of his implant that would defeat the way in which it works by sealing out synovial fluid.

Thus, while Campbell discloses a xenograft BTB implant, Campbell also teaches away from changing the **“details of [its] construction,”** i.e., its stopper (frustoconical) shaped bone blocks, or its **“manner”** of implantation to some other shape or manner, such as implants shaped for sliding and fixing in bone tunnels which would inherently allow synovial fluid to enter the bone tunnel. Consistent with Campbell’s teaching away, FIG. 6 of Beck discloses space in the bone tunnel between sidewall 12 of the bone tunnel and interference screw 30 into which synovial fluid can migrate. Because the primary reference, Campbell, teaches away from BTB implants that use bone tunnels and interference screws (i.e., Beck), Campbell cannot be combined with Beck.

Moreover, Campbell teaches away from Applicants’ xenograft BTB implants, which are structured for use with bone tunnels. In the present case as in *Fine*, the cited reference (Campbell) **seeks to avoid** and **warns against** the use of bone tunnels and the implants used in bone tunnels. *See In re Fine*, 5 USPQ2d at 1599 (“So, instead of suggesting that the system be used to detect nitrogen compounds, Eads deliberately **seeks to avoid** them; it **warns against** them rather than teaches Fine’s invention.”); emphasis added in bold. The *Fine* Court then held “In the face of this, one skilled in the art would not be expected to combine a nitrogen-related detector with the Eads’ system.” *Id.* Likewise, in the present case, one skilled in the art would not be expected to combine the xenograft BTB of Campbell with the implants and features that Campbell expressly taught away from. For all these reasons, claims 1, 2, 4, 8-9, and 31-40 would not have been obvious under 35 U.S.C. §103(a) over U.S. Pat 5,067,962 (“Campbell”) in view U.S. Patent No. 5,961,520 (“Beck”).

**C. Logic and the Larson and Olsen Declarations establish as Fact that there is no Known Method for using (installing) the implant of Campbell modified with the groove of Beck**

“Before obviousness may be established, the examiner must show that there is either a suggestion in the art to produce the claimed invention or a compelling motivation based upon sound scientific principles.” *Ex Parte Kranz*, 19 USPQ2d 1216,

1218 (Fed. Cir. 1991). “Logic compels that the suggestion or motivation be accompanied by a **general knowledge** of the **existence of art recognized techniques** for carrying out the proposed invention.” *Ex Parte Kranz*, 19 USPQ2d at 1218. In the present case, the Applicants rely upon both logic and declarations of those skilled in the art to establish that “**art recognized techniques**” did not exist for using (implanting) the allegedly obvious invention.

### 1. The allegedly obvious invention

The Patent Office contends that “[t]he only relationship between the Campbell et al. reference and the Beck, Jr. et al reference is the **simple** installation of an **interference screw** to lock the ligament to the patient’s bone.” As discussed above, Campbell discloses a xenograft BTB implant comprising stopper (frustoconical) shaped bone blocks at opposing ends of a tendon, that are implanted by a manner wherein the knee must be “open” to drill the corresponding frustoconical holes in the femur and tibia for receiving the bone blocks. [Larson Declaration at ¶ 6.] The first bone block may be inserted in the corresponding hole in the tibia or femur and locked in place with the knee open or closed. However, because the tendon between the bone blocks must be sufficiently short to tightly hold the tibia and femur in adjacent juxtaposition, the “open” knee must then be closed to insert the second bone block in the opposing hole in the “femur” or “tibia” respectively. With the knee now in the closed position, the second bone block is pressed tightly into position in its hole (which also tensions the tendon) by a thin probe inserted into the closed knee joint. A drill is then positioned for drilling a hole through the “femur” or “tibia” and through the stopper shaped bone block of the implant. Once the hole is drilled, a pin is inserted in the hole through “femur” or “tibia” and the stopper shaped implant, thereby holding the second stopper shaped bone block in place and providing a tensioned ligament between the tibia and femur. *See* FIG. 4 of Campbell and Campbell at col. 4, lines 29-40. The Patent Office contends that it would have been obvious to substitute the grooves of Beck on the bone blocks of Campbell so as to insert the implant of Campbell with an interference screw. The Applicants respectfully submit that Campbell teaches away from the bone blocks of the Applicants’ claims, as amended, wherein the bone blocks are shaped to be slideably mounted in bone tunnels. *See* Section

I(B) *supra*. Secondly, if a groove were placed on the bone blocks of Campbell, logic and the Larson and Olsen declarations establish that there were no “art recognized techniques” for installing an implant so modified.

## 2. The Larson and Olsen Declarations

As stated in *Ex Parte Kranz*, it is the Patent Office’s burden to prove that there exists “art recognized techniques” for installing the stopper shaped BTB of Campbell with an interference screw. 19 USPQ2d at 1218. However, in the present case, the Patent Office has failed to show that “art recognized techniques” existed for installing the BTB implant of Campbell wherein both of the bone blocks were modified to contain a groove for an interference screw. In contrast, the Applicants submitted the declarations of two persons skilled in the BTB art, Dr. Larson and Mr. Olsen, who established as fact that “art recognized techniques” did not exist for what the Patent Office contends is “the **simple** installation of an interference screw to lock the ligament to the patient’s bone” using Campbell’s stopper shaped bone blocks. In the absence of an “art recognized technique” for using (implanting) the stopper shaped implant of Campbell modified with the grooves of Beck, there would be no motivation for one skilled in the art to make something that could not be installed. *See In re Chu*, 36 USPQ2d 1089, 1095 (Fed. Cir. 1995) (“Although a prior art device could have been turned upside down, that did not make the modification obvious unless the prior art suggested the desirability of turning the device upside down.”).

In particular, Larson and the Olsen declarations establish as fact that there **did not exist an art recognized techniques for carrying out the proposed invention** wherein the xenograft BTB of Campbell, having its stopper shaped bone blocks, were modified to contain the groove of Beck for accommodating an interference screw. According to Dr. Larson, if “one skilled in the art wanted to implant the BTB of Campbell that was modified to include grooves for interference screws, it would require a combination of techniques that was neither taught or suggested in Campbell or Beck.” [Larson Declaration at ¶11.] “Rather, the combination was negated by the teachings in both Campbell and Beck.” [Larson Declaration at ¶11.] “An interference screw could theoretically be positioned through an endosteal tunnel and then screwed in between the groove on the donor bone plug and the recipient bone to fix the donor bone plugs (albeit

poorly).” [Larson Declaration at ¶11.] “However, this method is expressly taught away from by Campbell because the synovial fluid would flow unabated into the open endosteal tunnels.” [Larson Declaration at ¶11.] “So, therefore if I were to adhere to the essence of the concepts presented in Campbell, and Campbell’s important “manner” of implantation, I would perform an open arthrotomy incision (a large incision), not use endosteal tunnels, and fixate the graft transversely [with pins], as did Campbell.” [Larson Declaration at ¶12.].

In the Olsen Declaration, Mr. Olsen declares that based upon his education listed in paragraphs 2 and 3 of his declaration, and the experiences listed in paragraphs 4-6 of his declaration and in his curriculum vitae (Exhibit A), he considers himself to be “a person of ordinary skill in the art of BTB structure, testing and modes of implantation..” [Olsen Declaration at ¶7.] It is also significant that Mr. Olsen declares that he is a co-inventor on the four listed U.S. patents related to endosteal ligament mounting and ACL repairs. [Olsen Declaration at ¶6.] Mr. Olsen further declares that he has reviewed “the above-identified patent application, the rejected claims, the Official Action of 09/28/04 and the cited art” and that he understands their contents. [Olsen Declaration at ¶ 8.]

After reviewing the patent application, the rejected claims, the Official Action of 09/28/04 and the cited art, Mr. Olsen disagrees with the Patent Office’s conclusion that “[i]t would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the bone blocks of the Campbell et al reference with **the longitudinal groove (see surface 17) of the Beck, Jr. et al. reference**, in order to insert an attachment screw and attach the attachment system to the patient’s bone.” [Olsen Declaration at ¶8.]

As factual support for his conclusion, Mr. Olsen points out that at the filing date of the present application, there were two techniques for performing anterior cruciate ligament repair- the open technique and the endosteal technique. [Olsen Declaration at ¶9.] These are the same techniques referenced in ¶6 of the Larson Declaration. Mr. Olsen, like Dr. Larsen, declares that Campbell teaches the surgical technique wherein the knee is “opened such that the femur and the opposing tibia are partially disarticulated” and then the bone blocks are inserted into their respective holes. [Olsen Declaration at ¶10.] Mr. Olsen, like Dr. Larsen, declares that Beck discloses the endosteal technique wherein bone tunnels are drilled “through the tibia and into the femur” as shown in his U.S. Pat.

6,306,168 at FIGs. 10 and 11 at element 10 (“femoral tunnel), and where the ends (anchor bodies) of the BTB are fixed in place in the endosteal tunnels by an interference screw. [Olsen Declaration at ¶11.] Mr. Olsen declares that “one skilled in the art would have no reason or motivation to put a groove on the bone block of Campbell.” [Olsen Declaration at ¶12.] In particular, Mr. Olsen declares that if one skilled in the art added the grooves of Beck to the BTB of Campbell and employed Campbell’s open technique, one skilled in the art would not would not be able to insert the second interference screw in the joint which must be closed to seat the second bone block in its respective hole:

I will assume for the sake of argument that one added the grooves of Beck to the BTB of Campbell. **A first screw could be inserted to fix one bone block of the BTB of Campbell to the corresponding hole in the femur because the joint is open and accessible to a screw and a driver for inserting the screw. However, when the second bone block is fixed in the corresponding hole in the tibia, it is desirable for the sake of proper tensioning and isometry that the joint be in a shallow degree of flexion thus closing access to the second bone block. Neither Beck nor Campbell teaches how to insert the second screw in a closed joint.** This is why Campbell used stainless steel pin 32 in hole 26 that traversed the tibia and the bone block. See Campbell at FIG. 4 and at col. 4, lines 38-40 (“There, it is attached to the tibia<sup>28</sup> by suitable means such as a second stainless steel pin 32 through hole 26.”). Thus, the combination of Campbell over Beck would not motivate one skilled in the art to put a groove in each of the bone blocks of Campbell’s BTB because the combination of Campbell and Beck (even if combinable) does not disclose how to use or install such a graft. Clearly, one skilled in the art would have no motivation to make a BTB that could not be installed, or that would require techniques neither taught nor suggested in Campbell or Beck. However, more importantly, Campbell and Beck are disclosing BTBs for use in very different techniques. Hence, it is my opinion and conclusion, as a person skilled in the art, that it would not have been obvious to take the groove feature of Beck and add them to the bone blocks of Campbell to create an invention that neither teaches how to use.

[Olsen Declaration at ¶13; emphasis added in bold.]

Thus, it is Mr. Olsen’s declared statement, as a person skilled in the art, that one skilled in the art would not have been motivated to place the groove of Beck on the bone blocks of

Campbell's BTB implant because the resulting BTB would be impossible to implant using either Campbell's open technique or Beck's closed technique. Likewise, Dr. Larson said above that he could not have implanted a BTB of Campbell with the groove by the either of the techniques disclosed in Campbell or Beck. [Larsen Declaration at ¶¶9, 12 and 13.]

For all these reasons, the combination of U.S. Pat 5,067,962 ("Campbell") in view U.S. Patent No. 5,961,520 ("Beck") would not make a *prima facie* case of obviousness under 35 U.S.C. §103(a) against claims 1, 2, 4, 8-9, and 31-40 as originally filed or as amended. The allowance of claims 1-2, 4, 8-9 and 31-40 is respectfully requested.

**3. Logic also Establishes that the BTB of Campbell modified with a Groove could not be installed by the "open" technique of Campbell or the endosteal technique of Beck**

Campbell discloses a BTB implant having opposing stopper shaped (frustoconical) bone blocks that fit in corresponding stopper shaped holes in the tibia and femur, respectively. When the second bone block is seated (but not yet affixed) in its correspondingly shaped hole, the knee inherently becomes closed. By rough analogy, the closed knee joint is like the hinge of a closed door. In this closed position, it is impossible to add a screw to a hole in the mounting plate of the hinge to lock it in place, as the door covers the mounting plate. Likewise, in the closed knee, it is impossible to insert an interference screw so that it would hold the second bone block in place, as the bones of the knee would cover the proposed interference screw groove. Thus, the BTB implant of Campbell whose bone blocks were modified to have the groove of Beck could not be inserted by Campbell's open technique. Separately, it must be remembered that Campbell teaches away from use of a groove and an interference screw technique which would break the seal between the bone block and the recipient's bone, allowing synovial fluid from within the joint to enter the gap formed between the recipient bone and the bone block.

**D. The Other Secondary References cited by the Patent Office do not make up for the Teaching Away by Campbell**

The Patent Office cites to three other references: Simon (U.S. Pat. 5,951,560) Mahoney (U.S. Pat. 5,282,802) and Roger (U.S. Pat. 5,383,878). Each is directed to an implant or an interference screw used with the bone tunnel technique. However, none of these secondary references addresses or makes up for Campbell's teaching away from the use of bone tunnels and BTB implants having bone blocks (or synthetic blocks) that are dowel shaped for sliding through such bone tunnels in a graft recipient. Moreover, Mahoney favors BTB grafts taken from the patient's own body (autografts) and teaches away from the use of allografts or artificial ligaments because of biocompatibility problems:

In most cases, however, using a natural part of the **patient's body** to replace the damaged ligament is **preferable**. **Artificial ligaments** have **biocompatibility and biodegradation problems** which a tendon section from the patient's own patella does not have.

[Mahoney at col. 2, lines 1-6; emphasis added in bold.]

Thus, xenografts, such as taught in Campbell which are more foreign than allografts or synthetic ligaments, would be even more unfavorable under Mahoney. For all these reasons, the cited art in any combination, would not make a *prima facie* case of obviousness under 35 U.S.C. §103(a) against claims 1, 2, 4, 8, 9, and 31-40 3, 7-11 as originally filed or as amended. The allowance of claims 1-2, 4, 8-9 and 31-40 is respectfully requested.

### CONCLUSION

Claims 1-2, 4, 8-9 and 31-40 stand rejected. In view of the amendments, arguments and evidence provided herein, all bases for rejecting claims 1-2, 4, 8-9 and 31-40 under 35 U.S.C. §103(a) for alleged obviousness have been rebutted. The allowance of claims 1-2, 4, 8-9 and 31-40 is respectfully requested.

If the Examiner feels that a telephone call would advance the prosecution of this application, he is invited to telephone the undersigned attorney at the telephone number provided below.

Respectfully submitted,

**McANDREWS, HELD & MALLOY, LTD.**

By:



Donald J. Pochopien  
Registration No. 32,167  
Attorney for Applicants  
500 West Madison Street  
34<sup>th</sup> Floor  
Chicago, Illinois 60661  
(312) 775-8133

Date: August 15, 2005

J:\open\Djp\Regeneration Technologies\USPTO\13921US03 Resp 1.111 '05.doc